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Products of Unicity International are distributed through independent distributors.

BIO-C™

[biō sē]

OTC

DESCRIPTION

Bio-C™ is a vitamin C nutritional supplement. Bio-C™ is a yellow, water-soluble, crystalline powder pressed into a tablet. Each Bio-C™ tablet consists of a proprietary blend of ascorbyl palmitate, calcium ascorbate, ascorbic acid, magnesium ascorbate and 75 mg of citrus bioflavonoids. In addition to the active ingredients, each 803 mg tablets contains dextrose, microcrystalline cellulose, silicon dioxide, magnesium stearate, and stearic acid.

BENEFITS AND RESEARCH

Vitamin C (ascorbic acid) is a water-soluble vitamin that is used in the body to form cartilage, collagen, muscles and blood vessels. Vitamin C is a potent antioxidant that can protect small molecules such as proteins, carbohydrates, nucleic acids and lipids from damage caused by free radicals that are generated through the course of normal metabolism or through exposure to external toxins and pollutants (e.g. ultraviolet radiation from the sun or smoking). Vitamin C can also regenerate other antioxidants like vitamin E. Additionally, vitamin C is required for the synthesis of carnitine, a molecule involved in the transport of fats across the mitochondrial membrane, as well as the synthesis of norepinephrine, a neurotransmitter.*

USAGE

Take one tablet morning and night with a meal.

SAFETY AND WARNINGS

Bio-C™ is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement.

HOW SUPPLIED

Available in tablets.

REFERENCES

Carr, AC and Frei B. (1999), American Journal of Clinical Nutrition 96: 1086-1107.
 Jacob, RA and Sotoudeh G. (2002), Nutrition in Clinical Care 5: 66-74.
 Deruelle F, Baron B. (2008), Journal of Alternative and Complementary Medicine 14:1291-1298.
 Levine M, Rumsey SC, Daruwala R, Park JB, Wang Y. (1999), The Journal of the American Medical Association 281: 1415-1423.

* THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

BIOS LIFE® C

[bi-ōs lif sē]

Advanced Fiber and Nutrient Drink

OTC

DESCRIPTION

Bios Life® C is a fiber-based, vitamin-rich nutritional supplement. Bios Life® C contains a blend of soluble and insoluble fibers, phytosterols, policosanol, an extract of *Chrysanthemum morifolium*, vitamins, and minerals that when combined with a healthy diet and exercise may lower total serum cholesterol, lower triglyceride levels and reduce the risk of heart disease.

Bios Life® C is light orange in color. It is a hygroscopic crystalline powder that is generally soluble in water. Each serving of Bios Life® C contains 3 g of fiber, 1 g of phytosterols, 6 mg of policosanol, and 12.5 mg of an extract of *Chrysanthemum morifolium*. In addition to these active ingredients, each serving of Bios Life® C contains maltodextrin, citric acid, orange juice powder, sucralose and orange flavor.

BENEFITS AND RESEARCH

It's estimated that Americans consume 10-12 g of total fiber per day, less than half the amount of the recommended daily intake. Epidemiological and clinical studies have correlated

low daily fiber intake with higher incidences of hyperinsulinemia, hypercholesterolemia, and elevated risks of cardiovascular disease.

Bios Life® C is a nutritional supplement designed to increase daily fiber intake. Each serving of Bios Life® C contains three grams of dietary fiber. When taken three times a day, this achieves nearly half of the recommended daily value of fiber. Fiber supplementation has been shown to decrease preprandial and postprandial glucose levels and lower LDL cholesterol and apolipoprotein B levels.

In addition to fiber supplementation, Bios Life® C contains a patented blend of phytosterols, policosanol, *Chrysanthemum morifolium*, vitamins and minerals. This blend of ingredients optimizes cholesterol levels through a combination of four mechanisms. First, the soluble fiber matrix prevents cholesterol reabsorption in the gastrointestinal tract through bile-acid sequestration. Second, the phytosterols reduce dietary absorption of cholesterol. Third, policosanol inhibits hepatic synthesis of cholesterol mediated through HMG-CoA reductase. Fourth, *Chrysanthemum morifolium* provides phytonutrients that enhance conversion of cholesterol to 7- α -hydroxycholesterol. The four mechanisms provide a synergistic approach to optimizing cholesterol levels. Research has shown that this product may serve as a first line treatment option for mild hypercholesterolemia, as well as adjunct therapy for lipid lowering pharmaceutical intervention.

SUGGESTED USAGE

Dissolve the contents of one packet or one scoop into 8 to 10 fl. oz. of liquid (water or juice) and stir vigorously. Drink immediately. Use 15-20 minutes prior to meals up to three times daily.

SAFETY AND WARNINGS

Bios Life® C is well tolerated. There may be mild gastrointestinal discomfort, such as increased flatulence or loose stools, during the first month of initial use due to the increased uptake of dietary fiber. This GI disturbance usually disappears within the first thirty days. If the GI discomfort persists, reduce the number of servings of Bios Life® C. If the GI discomfort further persists, stop taking the product and consult your physician. Taking this product without adequate liquid can result in complications. If you are a diabetic, consult a physician for proper use of this product, as the chromium may reduce the need for medication.

HOW SUPPLIED

Bios Life® C is packaged in single-serving foil packets or in bulk canisters.

REFERENCES

Sprecher, DL and Pearce GL (2002), Metabolism 51: 1166-70.
 Verdegem, PJE; Freed, S and Joffe D (2005), American Diabetes Association 65th Scientific Sessions, San Diego, CA.
 Duenas, V; Duenas, J; Burke, E and Verdegem, PJE (2006), 7th International Conference on Arteriosclerosis, Thrombosis, and Vascular Biology, American Heart Association, Denver, CO.
 Verdegem, PJE (2007), Current Topics in Nutraceutical Research 5: 1-6
 US Patent 6,933,291.

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Shown in Product Identification Guide, page 329

BIOS LIFE® SLIM™

[bi-ōs lif slim]

Advanced Fiber and Nutrient Drink

OTC

DESCRIPTION

Bios Life® Slim™ is a fiber-based, vitamin-rich nutritional supplement. Bios Life® Slim™ contains a blend of soluble and insoluble fibers, Unicity® 7 \times technology, phytosterols, policosanol, an extract of *Chrysanthemum morifolium*, vitamins, and minerals that when combined with a healthy diet and exercise may lower total serum cholesterol, reduce the risk of heart disease and help achieve and maintain a healthy body weight.

Bios Life® Slim™ is light orange in color. It is a hygroscopic crystalline powder that is generally soluble in water. Each serving of Bios Life® Slim™ contains 4 g of fiber, 1 g of phytosterols, 750 mg of Unicity 7 \times , 6 mg of policosanol and 12.5 mg of an extract of *Chrysanthemum morifolium*. In addition to these active ingredients each serving of Bios Life® Slim™ contains maltodextrin, citric acid, orange juice powder, sucralose and orange flavor.

BENEFITS AND RESEARCH

It's estimated that Americans consume 10-12 g of total fiber per day, less than half the amount of the recommended daily

intake. Epidemiological and clinical studies have correlated low daily fiber intake with higher incidences of obesity, hyperinsulinemia, hypercholesterolemia, and elevated risks of cardiovascular disease.

Bios Life® Slim™ is a nutritional supplement designed to increase fiber intake. Each serving of Bios Life® Slim™ contains four grams of fiber. When taken three times a day this achieves half of the recommended daily value of fiber. Fiber supplementation has been shown to decrease preprandial and postprandial glucose levels; lower LDL cholesterol and apolipoprotein B levels; increase satiety and facilitate weight loss.

In addition to fiber supplementation, Bios Life® Slim™ contains a patented blend of phytosterols, policosanol, *Chrysanthemum morifolium*, vitamins and minerals. Bios Life® Slim™ facilitates weight loss through five distinct mechanisms. First, the soluble fiber matrix promotes an increase in satiety. Second, Bios Life® Slim™ improves cholesterol levels. Reduction in LDL content removes a potent inhibitor of lipolysis. Third, Bios Life® Slim™ improves blood glucose levels. Maintaining appropriate serum glucose levels reduces hyperinsulinemia and promotes insulin sensitivity. Reducing insulin levels permits fatty acid oxidation to occur. Fourth, Bios Life® Slim™ restores appropriate leptin signaling. Lastly, Bios Life® Slim™, reduces triglyceride levels allowing for leptin to cross the blood-brain barrier and effect its mechanism of action. Research has shown that this product may serve as a first line treatment option for mild hypercholesterolemia, as well as adjunct therapy for lipid lowering pharmaceutical intervention.

SUGGESTED USAGE

Dissolve the contents of one packet or one scoop into 8 to 10 fl. oz. of liquid (water or juice) and stir vigorously. Drink immediately. Use 15-20 minutes before meals up to three times daily.

SAFETY AND WARNINGS

Bios Life® Slim™ is well tolerated. There may be mild gastrointestinal discomfort, such as increased flatulence or loose stools, during the first month of initial use due to the increased uptake of dietary fiber. This GI disturbance usually disappears within the first thirty days. If the GI discomfort persists, reduce the number of servings of Bios Life® Slim™. If the GI discomfort further persists, stop taking the product and consult your physician. Taking this product without adequate liquid can result in complications. If you are a diabetic, consult a physician for proper use of this product, as the chromium may reduce the need for medication.

HOW SUPPLIED

Bios Life® Slim™ is packaged in single-serving foil packets or in bulk canisters.

REFERENCES

Sprecher, DL and Pearce GL (2002), Metabolism 51: 1166-70.
 Verdegem, PJE; Freed, S and Joffe D (2005), American Diabetes Association 65th Scientific Sessions, San Diego, CA.
 Slavin, JL, (2005) Nutrition 21: 411-418.
 Delzenne NM, Cani PD, (2005) Current Opinion Clinical Nutrition & Metabolic Care 8: 636-640
 Duenas, V; Duenas, J; Burke, E and Verdegem, PJE (2006), 7th International Conference on Arteriosclerosis, Thrombosis, and Vascular Biology, American Heart Association, Denver, CO.
 Verdegem, PJE (2007), Current Topics in Nutraceutical Research 5: 1-6
 US Patent 6,933,291.

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BONEMATE® PLUS

[bōn-māt plūs]

Advanced Bone Health Formula

OTC

DESCRIPTION

BoneMate® Plus is specially formulated to help maintain optimal bone health.* It contains three forms of calcium and vitamin D to maximize absorption and aid in the support of healthy bones, teeth, nerves, heart, and muscle tissue.

BoneMate® Plus is a light gray in color and is soluble in water. Each serving of BoneMate® Plus contains the following active ingredients 600mg of calcium, 300mg of magnesium, 30 mg of vitamin C, 2000 IU of vitamin D, 0.5mg of boron, 5 mg of zinc, 1mg of manganese, 1mg of copper, and 20mg of vitamin K. In addition, it also contains the inactive ingredients microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

BENEFITS AND RESEARCH

Calcium is the most common mineral in the body. Almost 99% of the calcium in our body is found in the bones and teeth. Bone is a dynamic tissue that is constantly being remodeled throughout our lives. A chronically low calcium intake in growing individuals may prevent the attainment of optimal peak bone mass. Once peak bone mass has been achieved, inadequate calcium intake may contribute to accelerated bone loss and eventually to osteoporosis.

Vitamin D, a secosteroid that is produced by the body upon exposure to the sun, is required for optimal calcium absorption. To ensure that calcium absorption is not limited by inadequate vitamin D levels, BoneMate® Plus contains 2000 IU of vitamin D per serving. In addition to facilitating calcium absorption, Vitamin D has been shown to target over 2000 different genes in the body. Vitamin D deficiency has been associated with increased risks for heart disease, stroke, diabetes, depression, osteoarthritis, chronic pain, and osteoporosis.

USAGE

Take two tablets twice daily with a meal.

SAFETY AND WARNINGS

BoneMate® Plus is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement. The Food and Nutrition Board of the Institute of Medicine has set the tolerable upper level (UL) of intake for calcium in adults at 2,500 milligrams (mg) of calcium/day.

HOW SUPPLIED

Available as tablets or as a powder.

REFERENCES

Weaver CM, Heaney RP. Calcium. In: Shils M, Olson JA, Shike M, Ross AC, eds. *Modern Nutrition in Health and Disease*. 9th ed. Baltimore: Williams & Wilkins; 1999: 141-155.

Heaney RP. Calcium, dairy products and osteoporosis. *J Am Coll Nutr*. 2000;19(2 Suppl):83S-99S.

Food and Nutrition Board, Institute of Medicine. *Calcium. Dietary Reference Intakes: Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. Washington, D.C.: National Academy Press; 1997:71-145.

Reid IR. Therapy of osteoporosis: calcium, vitamin D, and exercise. *Am J Med Sci* 1996;312:278-86. *Food and Nutrition Board, Institute of Medicine. Calcium. Dietary Reference Intakes: Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. Washington, D.C.: National Academy Press; 1997:71-145.

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CARDIO-BASICS™

OTC

Caring for your heart*

DESCRIPTION

Cardio-Basics™ is a nutritional supplement that combines multivitamins, minerals and antioxidants to support the cardiovascular system.

Cardio-Basics™ is a light orange, water-soluble powder pressed into tablets. Each tablet of Cardio-Basics™ contains the following vitamins, minerals, amino acids and antioxidants: beta-carotene (vitamin A), thiamine (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), calcium d-pantothenate (vitamin B5), pyridoxine hydrochloride (vitamin B6), folate (vitamin B9), cyanocobalamin (vitamin B12), ascorbic acid and ascorbyl palmitate (vitamin C), cholecalciferol (vitamin D), d-alpha-tocopherol (vitamin E), biotin, calcium, chromium, copper, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc, L-arginine, L-carnitine, L-cysteine, L-lysine, L-proline, inositol, coenzyme Q10, and maritime pine extract. In addition to those active ingredients each tablet also contains microcrystalline cellulose, sucrose, fatty acid esters, silicon dioxide, magnesium stearate, and maltodextrin.

BENEFITS AND RESEARCH

According to the Center for Disease Control and Prevention, one American will die every minute as a result of heart disease. Narrowing of the arterial walls can lead to blocked blood flow to the brain. A healthy lifestyle including being physically active, not smoking, and making good food choices can lead to a reduction of heart disease. Cardio-Basics™ provides the vitamins, minerals and antioxidants needed for a healthy heart. In clinical studies, participants using Cardio-Basics™ and Bio-C™ saw a significant reduction in arterial wall thickness, removal of calcification deposits and a reduced risk for cardiovascular disease when compared to the placebo group. Cardio-Basics™ provides the body with the necessary vitamins and minerals needed to support a healthy vascular system.*

SUGGESTED USE

Take two tablets daily with food.

SAFETY AND WARNINGS

Cardio-Basics™ is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement.

HOW SUPPLIED

Available in tablets

REFERENCES

Niedzwiecki, A, Rath, M. (1996) *Journal of Applied Nutrition*, 48: 67-78.

Jeejeebhoy, F, Keith, M, Freeman, M, Barr, A, McCall, M, Kurian, R, Mazer, D, Errett, L, (2002), *American Heart Journal* 143: 1092-1100.

Verdgem, PJE, Lonky, S, Curley, S. (2005) 7th Conference on Arteriosclerosis, Thrombosis and Vascular Biology.

Lloyd-Jones D, Adams R, Carnethon M, DeSimone G, Ferguson TB, Flegal K, Ford E, Furie K, Go A, Greenlund K, Haase N, Hailpern S, Ho M, Howard V, Kissela B, Kittner S, Lackland D, Lisabeth L, Marelli A, McDermott M, Meigs J, Mozaffarian D, Nichol G, O'Donnell C, Roger V, Rosamond W, Sacco R, Sorlie P, Stafford R, Steinberger J, Hong Y; (2009) *Circulation*, 119: 480-486.

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CARDIO-ESSENTIALS

OTC

Caring for your heart*

DESCRIPTION

Cardio-Essentials is a nutritional supplement for the heart. Cardio-Essentials contains Coenzyme Q-10, L-carnitine, L-taurine and Hawthorn berry.

Cardio-Essentials is a light tan, water-soluble powder. Each capsule of Cardio-Essentials contains 100 mg of Coenzyme Q-10 and 3.5 g of a blend of L-carnitine, L-taurine, and Hawthorn berry. In addition to those active ingredients, each capsule also contains silicon dioxide, stearic acid and calcium silicate.

BENEFITS AND RESEARCH

One of the leading causes of congestive heart failure (CHF), left ventricular dysfunction, affects approximately 1.5% of the population in the United States. CHF patients with left ventricular dysfunction have reduced levels of Coenzyme Q-10, L-carnitine and L-taurine and have an enlarged left ventricle. In a clinical study, the combination of L-carnitine, L-taurine, and Coenzyme Q10 was shown to benefit congestive heart failure patients by reducing left ventricular size. These ingredients are known to be important in providing adequate energy for heart muscle. Cardio-Essentials provides adequate amounts of these ingredients, i.e. 100 mg of CoQ10. Hawthorn extract is traditionally used in supporting the heart function.

SUGGESTED USE

Take three capsules twice a day with food.

SAFETY AND WARNINGS

Cardio-Essentials is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement.

HOW SUPPLIED

Available in capsules

REFERENCES

Jeejeebhoy, F et al (2002), *American Heart Journal* 143 1092-1100.

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CM PLEX™ AND CM PLEX™ CREAM

OTC

[CM plēks]

Proprietary fatty acid blend to help alleviate symptoms of osteoarthritis*

DESCRIPTION

CM Plex and CM Plex Cream are a softgel and topical cream, respectively, that contain a proprietary blend of cetylated fatty acids, soy and fish oil.

CM Plex is an opaque powder that is insoluble in water. One softgel capsule of CM Plex contains 350 mg of cetylated

fatty acids, 160 mg of soy oil and 25 mg of salmon oil. In addition to these active ingredients, each softgel capsule contains glycerin and St. John's Bread.

CM Plex Cream is an off-white powder that is insoluble in water. One gram of CM Plex Cream contains 7.7 mg of cetylated fatty acids and olive oil. In addition to these active ingredients CM Plex Cream also contains glyceryl stearate, glycerin, lecithin, tocopheryl acetate, benzyl alcohol, phenoxyethanol, carbomer, PEG-100 stearate, sodium hydroxide, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben and citrus aurantium bergamia (Bergamot) fruit oil.

BENEFITS AND RESEARCH

Cetyl myristoleate and related fatty acids have been proven to improve joint health through their anti-inflammatory effects. A clinical study indicated that subjects exhibited improvements in knee flexion compared to placebo. A second study indicated the cream is effective for improving knee range of motion, ability to climb stairs, rise from a chair and walk, balance, strength, and endurance.*

SUGGESTED USE

Softgels: Take one to two softgels three times daily with meals.

Cream: Apply generously onto clean skin and gently massage until the cream disappears. Repeat 3 to 4 times daily as necessary. For maximum results combine both products.

SAFETY AND WARNINGS

CM Plex Softgels and Cream are well tolerated. Some gastrointestinal discomfort may be experienced with CM Plex Softgels as with any dietary supplement.

HOW SUPPLIED

CM Plex is available in soft gels and as a topical cream.

REFERENCES

Hesslink, R et al (2002), *Journal of Rheumatology* 29, 1708-1712.

Kraemer, WJ et al (2004), *Journal of Rheumatology* 31, 767-774.

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IMMUNIZEN®

OTC

[im mōō nī zēn]

DESCRIPTION

Immunizen® is a nutritional supplement for boosting the immune system.

Immunizen® is a modestly water soluble, white crystalline powder. Immunizen® consists of a proprietary ingredient blend of colostrum, arabinogalactan, 1,3, 1,6 yeast beta-glucans and lactoferrin. In addition to the active ingredients, each 835 mg capsule of Immunizen® contains natural gelatin, stearic acid and silicon dioxide.

BENEFITS AND RESEARCH

Immunizen® combines the positive immune modulating effects of colostrum, arabinogalactans, yeast beta-glucans and lactoferrin to boost your body's natural defenses to foreign antigens. Colostrum is composed of immunoglobulins that bolster the body's immune system by providing immunity against various pathogens.

Beta-glucans are generally derived from the cell walls of the yeast species *Saccharomyces cerevisiae*. Beta-glucans are potent immuno-modulating agents that prime both the innate and adaptive immune systems.

USAGE

Take six capsules with water one to two hours before a meal for 10 days as needed.

SAFETY AND WARNINGS

Immunizen® is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement.

HOW SUPPLIED

Available in capsules.

REFERENCES

Lilius EM, Marnila P. (2001), *Current Opinion in Infectious Diseases* 14:295-300.

Hammarström L, Weiner CK. (2008), *Advances in Experimental Medicine and Biology* 606: 321-343.

Chan GC, Chan WK, Sze DM. (2009), *The Journal of Hematology and Oncology*, 2: 25-

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Immunizen—Cont.

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OMEGALIFE-3™
[*ōmēgā-līf 3*]**OTC****Omega-3 Fatty Acid Supplementation****DESCRIPTION**

OmegaLife-3™ is a blend of omega-3 fatty acids designed to help maintain healthy cardiovascular and cerebral function as well as aiding in the prevention of age-related macular degeneration.

OmegaLife-3™ is an amber-colored, semi-viscous, fat-soluble liquid. Each serving of OmegaLife-3™ contains the following active ingredients: 800 mg eicosapentaenoic acid (EPA), 400 mg docosahexaenoic acid (DHA), and vitamin E. In addition, it also contains the inactive ingredients gelatin, glycerin, purified water, and orange oil. OmegaLife-3™ has been molecularly distilled to ensure exceptionally pure oil and includes orange oil to prevent a fishy after taste.

BENEFITS AND RESEARCH

Clinical research suggests that fish oil can help support proper brain and visual function. In 2002 the FDA approved supplementation of DHA in infant formula. DHA is potentially important in fetal and infant neural development, in that DHA and arachidonic acid have been shown to be incorporated into brain and retinal cell membranes—particularly during the third trimester and early infant life. DHA is the predominant structural fatty acid in the central nervous system and in the retina of the eyes.

EPA supports the synthesis of important compounds in the body. EPA is the precursor of thromboxane and leukotriene, compounds involved in supporting healthy circulation. They also promote healthy blood vessels.*

Evidence is accumulating that increasing intakes of EPA and DHA can decrease the risk of cardiovascular disease by preventing arrhythmias, decreasing the risk of thrombosis, decreasing triglyceride levels, slowing the growth of atherosclerotic plaque, and decreasing inflammation.*

The U.S. Food and Drug Administration (FDA) has stated that, "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease."

USAGE

Take two softgels per day with a meal.

SAFETY AND WARNINGS

OmegaLife-3™ is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement. Common side effects include a "fishy" taste upon eructation.

HOW SUPPLIED

Available in softgels.

REFERENCES

Barter P, Ginsberg HN. Effectiveness of combined statin plus omega-3 fatty acid therapy for mixed dyslipidemia. *Am J Cardiol.* 2008 Oct 15;102(8):1040-5

Lee JH, Harris WS, et al. Omega-3 fatty acids for cardioprotection. *Mayo Clin Proc.* 2008 Mar;83(3):324-32.

SanGiovanni JP, Chew EY, Sperduto RD, et al. The relationship of dietary omega-3 long-chain polyunsaturated fatty acid intake with incident age-related macular degeneration: AREDS report no. 23. *Arch Ophthalmol.* 2008 Sep;126(9):1274-9.

SanGiovanni JP, Parra-Cabrera S, Colditz GA, Berkey CS, Dwyer JT. Meta-analysis of dietary essential fatty acids and long-chain polyunsaturated fatty acids as they relate to visual resolution acuity in healthy preterm infants. *Pediatrics* 2000;105:1292-8.

Kris-Etherton PM, Harris WS, Appel LJ. Omega-3 fatty acids and cardiovascular disease: new recommendations from the American Heart Association. *Arterioscler Thromb Vasc Biol.* 2003;23(2):151-152.

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VISUTEIN®**OTC**[*vī s-u-tēn*]

Clinically proven to support healthy eyes and vision.*

DESCRIPTION

VISUTEIN® is a nutritional supplement for maintaining healthy eyes. VISUTEIN® contains lutein, anthocyanidins

from bilberry, N-acetyl cysteine, zinc, mixed carotenoids (β-carotene, α-carotene and zeaxanthin) and riboflavin. VISUTEIN® is a purple crystalline powder that is water soluble. In addition to the active ingredients lutein, anthocyanidins, N-acetyl cysteine, zinc, mixed carotenoids and riboflavin, each 600 mg capsule contains magnesium stearate.

BENEFITS AND RESEARCH

Antioxidants from the carotenoid chemical family, such as lutein and zeaxanthin, play an important role in eye health. Low concentrations of these compounds in the retina are associated with age-related macular degeneration (AMD). Supplementation with high levels of lutein can restore the lutein concentration in the retina. Further supplementation of vitamins C and E along with zinc, copper and β-carotene delayed the onset of AMD. Low glutathione levels have been shown to reduce protection of the eye against oxidative stress. N-acetyl cysteine has been shown to elevate glutathione levels in the retina. A recent clinical study with VISUTEIN® has shown that AMD patients experience clear improvements in visual acuity, contrast sensitivity, and recovery from a flash.*

USAGE

Take two capsules per day with a meal.

SAFETY AND WARNINGS

VISUTEIN® is well tolerated. Some gastrointestinal discomfort may be experienced as with any dietary supplement.

HOW SUPPLIED

Available in capsules.

REFERENCES

Newsome, DA and Meyers, L (2004), "A Randomized Prospective Clinical Trial of Two Commercially Available Ocular Diet Supplements", In press.

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Unimed Pharmaceuticals, Inc.

A Solvay Pharmaceuticals, Inc. Company
901 SAWYER ROAD
MARIETTA, GA 30062

www.solvaypharmaceuticals-us.com

FOR MEDICAL INFORMATION CONTACT:

GENERALLY:

Medical Information Department

(800) 241-1643 #8

SALES AND ORDERING:

Orders may be placed by calling this toll free number:

(800) 241-1643 #1

Fax # 770-578-5901

Mail orders should be sent to:

Solvay Pharmaceuticals

Customer Relations Department

901 Sawyer Road

Marietta, GA 30062

ANDROGEL®[*än drō-jēl*]

(testosterone gel)

1% for topical use

Rx only

Ⓢ

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AndroGel safely and effectively. See full prescribing information for AndroGel.

AndroGel® (testosterone gel) 1% for topical use CIII
Initial U.S. Approval: 1953

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

See full prescribing information for complete boxed warning

- Virilization has been reported in children who were secondarily exposed to testosterone gel (5.2, 6.2).
- Children should avoid contact with unwashed or uncleaned application sites in men using testosterone gel (5.2).

- Healthcare providers should advise patients to strictly adhere to recommended instructions for use (5.2).

RECENT MAJOR CHANGES

Boxed Warning 9/2009

WARNINGS AND PRECAUTIONS (5.2) 9/2009

INDICATIONS AND USAGE

AndroGel is an androgen indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary Hypogonadism (Congenital or Acquired) (1.1)
- Hypogonadotropic Hypogonadism (Congenital or Acquired) (1.1)

DOSAGE AND ADMINISTRATION

Recommended starting dose: 5 g for adult males, applied topically once daily (2.1).

Apply to clean, dry, intact skin of shoulders and upper arms and/or abdomen. Do NOT apply AndroGel to the genitals (2.1).

Dose adjustment for adult males: If serum testosterone level is below the normal range, adjust dose from 5 g to 7.5 g and from 7.5 g to 10 g (2.3).

DOSAGE FORMS AND STRENGTHS

AndroGel (testosterone gel) 1% for topical use is available as:

- 2 × 75 g pumps (each pump dispenses 60 metered 1.25 g doses) (3)
- 2.5 g packet or 5 g packet (3)

CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected prostate cancer (4, 5.1).
- Pregnant or breast feeding women. Testosterone may cause fetal harm (4)

WARNINGS AND PRECAUTIONS

Patients with benign prostatic hyperplasia (BPH) treated with androgens are at an increased risk for worsening of signs and symptoms of BPH (5.1).

Secondary exposure to testosterone in children and women can occur with use of testosterone gel (5.2). Cases of secondary exposure resulting in virilization of children have been reported (6.2).

Children and women should avoid contact with unwashed or unclothed application site(s) in men using testosterone gel.

To minimize the potential for transfer to others, patients using AndroGel should apply the product as directed and strictly adhere to the following (5.2):

- Wash hands with soap and water after application.
- Cover the application site with clothing after the gel has dried.
- Wash the application site thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated.

Signs of virilization in children and women and the possibility of secondary exposure to testosterone gel should be brought to the attention of the healthcare provider. Testosterone gel should be promptly discontinued until the cause of the virilization is identified (5.2).

Due to lack of controlled evaluations in women and potential virilizing effects, AndroGel is not indicated for use in women (5.3).

Exogenous administration of androgens may lead to azoospermia (5.4).

Edema may be a complication in patients with preexisting cardiac, renal, or hepatic disease (5.6, 6.2).

Gynecomastia, enlargement of breast, may develop (5.7).

Sleep apnea may occur in those with risk factors (5.8).

Monitor serum testosterone, prostatic specific antigen, hemoglobin, hematocrit, liver function test, and lipid levels periodically (2.3, 5.1, 5.9).

Alcohol-based gels are flammable until dry (5.10).

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 5%) are acne, application site reaction, abnormal lab tests, and prostatic disorders (6).

Cases of testosterone secondary exposure resulting in virilization of children have been reported (6.2). Reported signs and symptoms have included enlargement of the penis or clitoris, premature development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases with a reported outcome, these signs and symptoms were reported to have regressed with removal of the exposure to testosterone gel (5.2, 6.2). In a few cases, however, enlarged genitalia did not fully return to age-appropriate normal size and bone age remained modestly greater than chronological age.

To report SUSPECTED ADVERSE REACTIONS, contact Solvay Pharmaceuticals, Inc. at 1-800-241-1643 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Androgens may decrease blood glucose, and therefore insulin requirement in diabetic patients (7.1).